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September 24, 2002

Ms. Karin Ferriter  
Senior Legal Advisor  
Office of Patent Legal Administration  
Office of the Deputy Commissioner  
for Patent Examination Policy  
United States Patent and Trademark Office  
Washington, D.C. 20231

Patent

#22

Dear Ms. Ferriter:

This is in regard to the application for patent term extension of U.S. Patent No. 5,275,813 filed by the Regents of the University of California under 35 U.S.C. § 156. The veterinary biologic product claimed by the patent is Fel-O-Vax® FIV vaccine (Feline Immunodeficiency Virus Vaccine, Killed Virus), which was assigned VS Code No. 15A5.21.

A review of the Center for Veterinary Biologics official records indicates that this product was subject to a regulatory period before its commercial marketing, or use, as required under 35 U.S.C. § 156(a)(4). The applicable regulatory prelicense review under the Virus-Serum-Toxin-Act commenced with the submission of an Application for United States Veterinary Biological Product License dated May 4, 1998, and was completed with the issuance of the United States Veterinary Biological Product License dated March 14, 2002, a period of 1,390 days.

As required by 35 U.S.C. § 156(d)(2)(A), we will publish our determination of the applicable regulatory review period in the Federal Register and notify you of our determination.

Sincerely,

/s/ Richard E. Hill

Richard E. Hill, Jr., D.V.M.  
Director  
Center for Veterinary Biologics

cc:  
CVB-IC  
CVB-L

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FPD 9-30-02

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